K070752

STORZ
KARL STORZ ENDOSCOPY

510(k) SUMMARY

MAY - 1 2007

Sponsor/Submitter: Karl Storz Endoscopy – America, Inc.
600 Corporate Pointe
Culver City, CA 90230-7600
Phone: (310) 338-8100
Fax: (310) 410-5519

Contact Person: Crystal Dizol
Regulatory Affairs Associate
Email: cdizol@ksea.com

Date of Submission: April 26, 2007

Device Trade Name: Karl Storz Miniature Endoscope

Common Name: Flexible fiberscope

Classification Name: Nasopharyngoscope (flexible or rigid) and accessories

Regulation Number: 21 CFR 874.4760

Product Code: EOB

Predicate Device(s): Olympus Angioscope (K911278)
Olympus ENF Type XP Rhino-Laryngo Fiberscope (K013591, K011869)
KSEA Sialoendoscope (K012527)

Device Description: The KSEA Miniature Endoscope is a manually operated, reusable surgical device that is provided to the end-user in a non-sterile condition. The device is a flexible fiber optic telescope which utilizes fiber-optic technology to perform the intended use.

Indications for Use: The KSEA Miniature Endoscope is indicated for use in visualization of sinus anatomy and pathology.

Technological Characteristics: The KSEA Miniature Endoscope and its predicate devices are flexible fiber optic telescopes that use fiber optic technology to transmit an image from the distal to the proximal end of the device.

Summary of Substantial Equivalence: The KSEA Miniature Endoscope is substantially equivalent to the predicate devices since the basic features, design, and intended uses are similar. The minor differences between the KSEA Miniature Endoscope and the predicate devices raise no new issues of safety and effectiveness, as these design differences have no affect on the performance, function, or intended use of the devices. For a comparison between the KSEA Miniature Endoscope and the predicate devices, refer to the attached substantial equivalence chart.

Att: Substantial Equivalence Chart for Karl Storz Miniature Endoscope

KARL STORZ ENDOSCOPY

SUBSTANTIAL EQUIVALENCE CHART FOR KARL STORZ MINIATURE ENDOSCOPE, 11565

Manufacturer	Shaft Diameter	Working Length	Viewing Angle	Field of View	Optics	Intended Use
KSEA: 11565 Miniature Endoscope	**0.5 mm**	**100 cm**	**0°**	**70°**	**Fiber optic**	**Used for visualization of sinus anatomy and pathology.**
Olympus: Angioscope (K911278)	0.5 mm	130 cm	0°	75°	Fiber optic	Used for viewing the peripheral and/or coronary vessels.
Olympus: ENF Type XP Rhino-Laryngo Fiberscope (K013591, K011869)	1.8 mm	30 cm	0°	75°	Fiber optic	Used for observing the nasal cavity, larynx and pharynx.
KSEA: 11576 Sialoendoscope (K012527)	0.75 mm	30 cm	0°	70°	Fiber optic	Used for visualization of the surgical site in salivary gland diagnostic and therapeutic procedures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 1 2007

Karl Storz Endoscopy-America, Inc.
c/o Crystal K. Dizol
600 Corporate Pointe
Culver City, Ca 90230-7600

Re: K070752
Trade/Device Name: KSEA Miniature Endoscope
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope
Regulatory Class: Class II
Product Code: EOB
Dated: March 15, 2007
Received: March 19, 2007

Dear Ms. Dizol:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

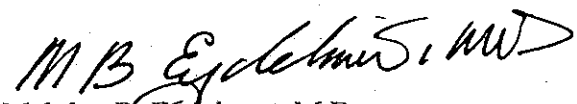
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K070752

510(k) Number (if known):

Device Name: KSEA Miniature Endoscope

Indications for Use: The Miniature Endoscope is indicated for use in visualization of sinus anatomy and pathology.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devices

510(k) Number K070752

Prescription Use: ✓ OR Over-The-Counter Use: _____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)